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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,953	06/24/2003	Steven C. Quay	02-03US	6874

36814 7590 08/08/2006

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,953	QUAY, STEVEN C.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-92* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration, the restriction requirement of December 20, 2005 is withdrawn in favor of the instant requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 82-92, drawn to JAM-1 peptides and derivatives, classified in class 530, subclass 329.

II. Claims 82-90, drawn to JAM-2 peptides, classified in class 530, subclass 330.

III. Claims 82-90, drawn to JAM-3 peptides, classified in class 530, subclass 330.

IV. Claim 82, drawn to occludin peptides, classified in class 530, subclass 325.

V. Claim 82, drawn to claudin peptides, classified in class 530, subclass 325.

VI. Claims 2-13, 15, 17 and 42-47, drawn to pharmaceutical compositions comprising JAM-1 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

VII. Claims 2-17,42-45 and 47, drawn to pharmaceutical compositions comprising JAM-1 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

VIII. Claims 2-17, 42-45 and 47, drawn to pharmaceutical compositions comprising JAM-1 peptides and a protein biologically active agent, classified in class 514, subclass 2.

IX. Claims 2-13 and 17, drawn to pharmaceutical compositions comprising JAM-1 peptides and a vaccine agent, classified in class 536, subclass 23.1.

X. Claims 2-7, 9, 12, 13, 15, 17 and 42-47, drawn to pharmaceutical compositions comprising JAM-2 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XI. Claims 2-7, 9, 12-17, 42-45 and 47, drawn to pharmaceutical comprising JAM-2 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XII. Claims 2-7, 9, 12-17, 42-45 and 47, drawn to pharmaceutical comprising JAM-2 peptides and a protein biologically active agent, classified in class 514, subclass 2.

XIII. Claims 2-7, 9, 12, 13 and 17, drawn to pharmaceutical comprising JAM-2 peptides and a vaccine agent, classified in class 536, subclass 23.1.

XIV. Claims 2-7, 9, 12, 13, 15, 17 and 42-47, drawn to pharmaceutical compositions comprising JAM-3 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XV. Claims 2-7, 9, 12-17, 42-45 and 47, drawn to pharmaceutical comprising JAM-3 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XVI. Claims 2-7, 9, 12-17, 42-45 and 47, drawn to pharmaceutical comprising JAM-3 peptides and a protein biologically active agent, classified in class 514, subclass 2.

XVII. Claims 2-7, 9, 12, 13 and 17, drawn to pharmaceutical comprising JAM-3 peptides and a vaccine agent, classified in class 536, subclass 23.1.

XVIII. Claims 1, 12, 13, 15, 17-23 and 30-47, drawn to pharmaceutical compositions comprising occludin peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XIX. Claims 1, 12-16, 18,-23, 30-45 and 47, drawn to pharmaceutical comprising occludin peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XX. Claims 1, 12-23, 30-45 and 47, drawn to pharmaceutical comprising occludin peptides and a protein biologically active agent, classified in class 514, subclass 2.

XXI. Claims 1, 12, 13, 18-23 and 30-41, drawn to pharmaceutical comprising occludin peptides and a vaccine agent, classified in class 536, subclass 23.1.

XXII. Claims 1, 12, 13, 15, 17 and 24-47, drawn to pharmaceutical compositions comprising claudin peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XXIII. Claims 1, 12-17, 24-45 and 47, drawn to pharmaceutical comprising claudin peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XXIV. Claims 1, 12-17, 24-45 and 47, drawn to pharmaceutical comprising claudin peptides and a protein biologically active agent, classified in class 514, subclass 2.

XXV. Claims 1, 12, 13, 17 and 24-41, drawn to pharmaceutical comprising claudin peptides and a vaccine agent, classified in class 536, subclass 23.1.

XXVI. Claims 49-51, 53, 58-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or

separately, JAM-1 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XXVII. Claims 49-51 and 58-65, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-1 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XXVIII. Claims 49-51 and 58-65, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-1 peptides and a protein biologically active agent, classified in class 514, subclass 2.

XXIX. Claims 49-51 and 58-65, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-1 peptides and a vaccine agent, classified in class 536, subclass 23.1.

XXX. Claims 53, 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-2 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XXXI. Claims 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-2 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XXXII. Claims 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-2 peptides and a protein biologically active agent, classified in class 514, subclass 2.

XXXIII. Claims 58-63, 66, 67 and 69, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-2 peptides and a vaccine agent, classified in class 536, subclass 23.1.

XXXIV. Claims 53, 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-3 peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XXXV. Claims 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-3 peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XXXVI. Claims 58-63, 66-69 and 81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, JAM-3 peptides and a protein biologically active agent, classified in class 514, subclass 2.

XXXVII. Claims 58-63, 66, 67 and 69, drawn to methods of coordinated administration and treating a disease or condition comprising administering,

together or separately, JAM-3 peptides and a vaccine agent, classified in class 536, subclass 23.1.

XXXVIII. Claims 48, 53-57, 64, 66-72 and 75-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, occludin peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XLIX. Claims 48, 54-57, 64, 66-72 and 75-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, occludin peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XL. Claims 48, 54-57, 64, 66-72 and 75-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, occludin peptides and a protein biologically active agent, classified in class 514, subclass 2.

XLI. Claims 48, 54-57, 64, 66, 67, 69-72 and 75-80, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, occludin peptides and a vaccine agent, classified in class 536, subclass 23.1.

XLII. Claims 48, 53-57, 64, 66-70 and 73-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, claudin peptides and a small molecule biologically active agent, classified in class 514, subclass 18.

XLIII. Claims 48, 54-57, 64, 66-70 and 73-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, claudin peptides and a peptide biologically active agent, classified in class 514, subclass 18.

XLIV. Claims 48, 54-57, 64, 66-70 and 73-81, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, claudin peptides and a protein biologically active agent, classified in class 514, subclass 2.

XLV. Claims 48, 54-57, 64, 66, 67, 69, 70 and 73-80, drawn to methods of coordinated administration and treating a disease or condition comprising administering, together or separately, claudin peptides and a vaccine agent, classified in class 536, subclass 23.1.

Claims 1 and 30-41 link(s) inventions 6-17. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1.

Claims 48, 52, 54, 70 and 75-80 link(s) inventions 26-37. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 48 and 54.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR § 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. § 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additional Restriction Requirement

Within Inventions VI-XLV, claims 17, 32, 70 and 76 recite approximately 536 million additional groups each, wherein the elements are related as subcombinations usable together (*see below*). Each claim recites 29 additional generic elements indicated as being optionally present in any combination, i.e. 1 or all 29 may be present. For example, one subcombination is (a) an aggregation inhibitory agent, another is (c) a pH control agent with (d) a degradative enzyme inhibitory agent, and yet another is (g)(i) a surfactant with (g)(x) cyclodextrin or a β-cyclodextrin derivative, (g)(v) an NO donor compound, and (f) a ciliostatic agent.

Thus, because the groups are too numerous to recite individually, Applicant is required to elect a single element, or combination of elements, if an election of any of Groups VI-XLV is made as part of the elected invention. This is not an election of species, but rather, an election of an invention.

Please note, the sub-elements of item (g) are improperly numbered, i.e.- there are two (ii) subgroups, and the claims indicate that one or more of (i)-(x) may be chosen, however there are 19 members of the group.

The inventions are independent or distinct, each from the other because of the following reasons:

Inventions I-V are directed to related compounds.

Inventions VI-XXV are directed to related compositions.

Inventions XXVI-XLV are directed to related methods.

The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the different peptides are structurally distinct from one another, are not obvious variants of each other and would be expected to have different effects and modes of operation. Furthermore, in the compositions and the methods of administering said compositions, the biologically active elements in each group are structurally distinct, are not obvious variants of another and would be expected to function differently, particularly since different biologically active agents are administered.

Inventions I-III and VI-XVII are related as combination and subcombination.

Inventions IV and XVIII-XXI are related as combination and subcombination.

Inventions V and XXII-XXV are related as combination and subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)).

In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination (inventions I-V, individually) is drawn

to an epitope of between 4 and 25 amino acids, while the combination of claim 1 is broader in scope embracing the protein as a whole, and with regards to JAM-, it embraces species not recited in the subcombination claims, e.g. JAM-4 and VE-JAM. The subcombination has separate utility such as modulators of inflammation or as Lewis antigens.

Further, as stated above, **within Inventions VI-XLV claims 17, 32, 70 and 76 define approximately 536 million inventions** that are related as subcombinations disclosed as usable together in a single combination.

The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. See MPEP § 806.05(d).

In the instant case, subcombination wherein the additional element is (g)(v) an NO donor compound, e.g. any of the compounds of US Patent 5,958,427, has separate utility such as useful in treating erectile dysfunction or treating hypertension, which is not a utility of a subcombination where the additional element is (c) a pH control agent, e.g. TRIS buffer.

Inventions VI-XXV and XXVI-XLV are related as product and process of use, respectively.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case the methods are generic to the condition being treated and can be practiced with any compound, e.g. saline solution to treat dry mucosal tissue. Furthermore, the products can be used for reducing metastasis or inhibition of inflammatory responses.

Inventions I-V and XXVI-XLV are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the compounds of Inventions I-V are not used in the methods of XXVI-XLV alone, and the methods require the presence of additional elements not found in the product claims.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Additionally, the compounds and compositions of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds and compositions is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using.

Because these inventions are independent or distinct for the reasons given above, the inventions require a different field of search (see MPEP § 808.02) and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Claims 1-17, 30-70 and 75-92 are generic to the following disclosed patentably distinct species of JAM-1 peptides and derivatives, too numerous to recite individually, including the species of SEQ ID NOs:1-10 and the species within Tables 2-5 of the specification.

Claims 1-9, 12-17, 30-48, 52-63, 66-70, 75-86, 89 and 90 are generic to the following disclosed patentably distinct species of JAM-2 peptides and derivatives, to numerous to recite individually, including the species recited in Table 6.

Claims 1-9, 12-17, 30-48, 52-63, 66-70, 75-86, 89 and 90 are generic to the following disclosed patentably distinct species of JAM-2 peptides and derivatives, to numerous to recite individually, including the species recited in Table 7.

Claims 1, 12-23, 30-48, 52-57, 71, 72 and 75-82 are generic to the following disclosed patentably distinct species of occludin peptides and derivatives, too numerous to recite individually, including the species of SEQ ID NOs:32-35 and 42 and those within Table 9.

Claims 1, 12-17, 24-29, 30-48, 52-57 and 73-82 are generic to the following disclosed patentably distinct species of claudin peptides and derivatives, including SEQ ID NOs:54-63 and the species recited within Table 8.

Claims 1-13, 15 and 17-81 are generic to the following disclosed patentably distinct species of biologically active small molecules, to numerous to recite individually, including the species of claims 15, 46, 47, 68 and 81, e.g. ketoprofen, ciclopirox or oleamide.

Claims 1-45 and 47-81 are generic to the following disclosed patentably distinct species of biologically active peptides, to numerous to recite individually, including the species of claims 15, 47, 68 and 81, e.g. oxytocin or cyclosporin.

Claims 1-45 and 47-81 are generic to the following disclosed patentably distinct species of biologically active proteins, to numerous to recite individually, including the species of claims 15, 47, 68 and 81, e.g. TPA, EGF, TGF or FSH.

The species are independent or distinct because the species are structurally distinct such that alone or in combination in the pharmaceutical, one species would not be an obvious variant over another, and the search of one would not lead to the discovery of any other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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